JUN 1 0 2003

510(k) SUMMARY

K031131

Applicant: Mölnlycke Health Care, Inc.
826 Newtown-Yardley Road
Newtown, PA 18940

Contact Person: Miguel A. Negron
Vice President,
Quality & Regulatory Affairs - North America
Tel.: 267-685-2078
Fax: 267-685-2010

Device Name:

Proprietary Name: Klinidrape® Surgical Drapes
Common/Usual Name: Surgical Drapes
Device Classification: Class II – 21 CFR 878.4370

Substantial Equivalence: For the purpose of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Mölnlycke Health Care considers the new Klinidrape® Surgical Drapes are substantially equivalent in function and intended use to our original Klinidrape® Surgical Drapes (K000906).

Intended Use: The Klinidrape® Surgical Drapes are devices intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

Description: The Klinidrape® Surgical Drapes are composed of a 3-laminate or 2-laminate composed of nonwoven, polyethylene film and white tissue.

Summary of Testing: The Klinidrape® Surgical Drapes have been found non-toxic and non-irritant when tested by the above biological tests in accordance with the ISO 10993, Part I: Biological Evaluation of Medical Devices. The materials used in the manufacturing of Klinidrape® Surgical Drapes have been tested in accordance with applicable standards and was determined to pass the Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood (ASTM-F1670-98) and the Viral Penetration testing (ASTM-F1671-97b). These materials were tested in accordance with 16 CFR 1610 and meet Class 1. The Klinidrape® Surgical Drapes have been tested and pass Tensile Strength and Elongation (ASTM D 882) and Breaking Strength (ASTM D 5034).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2003

Mr. Miguel A. Negron
Vice President
Mölnlycke Health Care, Incorporated
826 Newtown-Yardley Road
Newtown, Pennsylvania 18940

Re: K031131
Trade/Device Name: Klinidrape® Surgical Drapes
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: April 14, 2003
Received: April 15, 2003

Dear Mr. Negron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 9: Indications for Use Statement

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K031131
Unassigned

Mölnlycke Health Care, Inc.

Device Name: Klinidrape® Surgical Drapes

Indications for Use:

The Klinidrape® Surgical Drapes are devices intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031131

Prescription Use _____ Or Over-The-Counter Use _____
(Per 21 CFR 801.109)